REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As correctly indicated in the Office Action Summary, claims 1-6 are pending. No prohibited new matter has been introduced by this Amendment. Applicants reserve the right to pursue in a division or continuation application any subject matter canceled by way of this Amendment without prejudice or disclaimer.

The claims have been amended to place them in a more American format and to further clarify the subject matter Applicant regards as the invention. Support for the amendments to the claims is located at least in the claims as filed and throughout the specification, especially on page 2, lines 10-16.

I. OBJECTION TO THE DISCLOSURE

The disclosure was objected to for recitation in certain claims of "according to one of the preceding claims". Applicants respectfully turn the Examiner's attention to the Preliminary Amendment, submitted October 4, 1999, where the claims were amended to remove all references to multiple dependencies. A copy of the Preliminary Amendment as filed is enclosed for the Examiner's convenience. Entry of the Preliminary Amendment is

II. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-6 have been rejected under 35 U.S.C. § 112, second paragraph as indefinite because of the recitation of the term "propagating the viruses of each type or species on cells which are permissive for the viruses but which do not induce any viral interference". Claim 1 has been amended to recite "permissive for the viruses and do not induce any viral interference". Thus, all of the claims now in the application are free of this rejection. Withdrawal of the rejection is respectfully urged.

VII. REJECTIONS UNDER 35 U.S.C. § 102(b)

For proving anticipation, "anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." Jamesbury Corp. v. Litton Industrial Products, Inc. 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). The cited references do not describe or suggest all of the elements of the rejected claims, as discussed in greater detail below.

The present invention claims a method of determining the virus quantity of each species and/or serotype of a given virus species in a composition which contains different species and/or types of live virus. This method comprises propagating the virus species on cells permissive to the virus but not inducing viral interference and assaying each species of virus using a specific monoclonal antibody.

purportedly anticipated by Ibanez-Bernal et al. Ibanez-Bernal et al. (Medline Abstract

Medical and Veterinary Entomology, (1997) 11:305-309) is cited for purportedly disclosing that Vero cell cultured dengue virus serotypes 2 and 3 were identified by serotype-specific monoclonal antibodies. The present invention teaches a method of determining the quantity of different species or serotypes of a virus in a composition which contains different species or types of viruses. The claimed method comprises the propagation of the viruses present in the sample on cells which are permissive for the viruses and do not induce any viral interference. The method also comprises assaying each virus species using monoclonal antibodies. Applicants submit that Ibanez-Bernal et al. do not disclose the determination of different quantities of serotypes by the use of monoclonal antibodies, as claimed in the present invention. Rather, Ibanez-Bernal et al. merely disclose the detection of viruses by the observation of cythopathic effects followed by the identification of their serotype.

As the Ibanez-Bernal et al. reference does not anticipate the claimed invention, Applicants respectfully request the withdrawal of the rejection.

Shaw et al. Claim 5 was rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Shaw et al. Shaw et al. (Medline Abstract *Gastroenterology* (1987) 93:941-950) is cited for purportedly disclosing serotype-specific monoclonal antibodies directed at VP7 in a competitive solid-phase immunoassay to measure epitope specific immune responses to serotypes 1,2 and 3.

monoclonal antibodies. Some of these monoclonal antibodies are serotype-specific for

rotaviruses. However, unlike the claimed invention, not all of the monoclonal antibodies disclosed in Shaw et al. are serotype-specific. For example, the 2G4 disclosed in Shaw et al. is anti-VP3 which is heterotypically reactive to serotypes 3, 5 and 6.

Further, Shaw et al. fails to disclose the propagation of the viruses present in the sample on cells which are permissive for the viruses and do not induce any viral interference, as required by the claimed invention. Because the Shaw et al. reference does not anticipate the claimed invention, Applicants respectfully request the withdrawal of the rejection.

Osterhaus et al. Claim 6 was rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Osterhaus et al. Osterhaus et al. (Medline Abstract/ *Developments in Biological Standardization* (1981) 50:221-228) is cited for purportedly disclosing lymphocyte hybridomas which secrete monoclonal antibodies against different strains of polio virus types 1, 2 and 3.

Osterhaus et al. do not disclose or even suggest the methods of the claimed invention. The cited reference does not disclose the propagation of the viruses present in the sample on cells which are permissive for the viruses and do not induce any viral interference, as required by the claimed invention. Further, the cited reference fails to disclose the quantitative determination of the different species or types of viruses present in antibodies for use against the polio virus. On page 224 of the cited reference, the authors

of the paper disclose that the monoclonal antibodies may be useful for vaccine control purposes. Applicants submit that, as disclosed in the instant specification, the neutralization of monoclonal antibodies was well known in the art. However, the neutralization of monoclonal antibodies is not the inventive step of the instant invention. Rather, the propagation of the viruses present in the sample on cells which are permissive for the viruses and the quantitative determination of the different species or types of viruses present in the composition through the use of monoclonal antibodies are certain novel aspects of the present invention. As noted above, Osterhaus et al. do not disclose these required elements of the claimed invention.

As the Osterhaus et al. reference does not anticipate the claimed invention, Applicants respectfully request the withdrawal of the rejection.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Attachment to Reply and Amendment dated June 26, 2001

Marked-up Claims 1-6

1. (Twice amended) A method [Method] for determining the virus quantity of each of the virus types or virus species in a composition which contains different species or types of live virus, comprising the following steps:

- propagating the viruses of each type or species on cells which are permissive for the viruses and [but] which do not induce any viral interference, and
- assaying each type or species of virus using a specific monoclonal antibody.

2. (Twice Amended) The method [Method] according to claim 1, wherein the propagation is effected on Vero cells.

3. (Twice amended) The method [Method] according to claim 1, wherein the composition comprising different species or types of live virus is a vaccine composition.

4. (Twice amended) The method [Method] according to claim1, wherein the composition comprising different species or types of live virus is a composition which comprises four serotypes of live attenuated dengue virus.

5. (Twice Amended) The method [Method] according to claim 1, wherein the composition comprising different species or types of live virus is a composition which comprises three serotypes of live attenuated polio virus.

6. (Twice Amended) The method [Method] according to claim 1, wherein the composition comprising different species or types of live virus is a composition which comprises different types of rotavirus.